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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,168	07/31/2003	Bradley Kropp	85820.639	7538

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DUNLAP, CODDING & ROGERS P.C.  
PO BOX 16370  
OKLAHOMA CITY, OK 73113

EXAMINER

LANKFORD JR, LEON B

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/631,168

Applicant(s)

KROPP ET AL.

Examiner

Leon Lankford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,16-25,27-35,37-45,47-49 and 51-55 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,9,11,12,14,16-23,28-35,37-43,48,49 and 51-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,10,13,24,25,27,44,45 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of group II, in the reply is acknowledged. The traversal is on the ground(s) that the additional cells of groups III & IV do not render these groups patentably distinct. This is not found persuasive for the reasons of record and because the addition of distinct cells and cell types to a graft would clearly impart different, distinct properties and even utilities to the graft.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3, 6, 7, 10, 13, 24, 25, 27, 44, 45 & 47 have been considered on the merits.

All other claims are withdrawn as being drawn to non-elected inventions.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6, 7, 10, 13, 24, 25, 27, 44, 45 & 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There are many types of the generic "stem" cells and applicant has failed to show possession of the entire scope of "stem" cell. Applicant generically claims grafts and the use of "adult stem cell(s)" however the specification does not contain an adequate description for the entire scope of this terms and thus the claims. The written description requirement for a claimed genus, i.e. "stem cell" may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Also, given the limited showing of the specification, it does not appear that applicant possessed an actual effective method for repairing a damaged urinary tract tissue of a subject. Applicant should show where the demonstration of actual possession of this invention is shown.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6, 7, 10, 13, 24, 25, 27, 44, 45 & 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims a graft and method of making and using said graft however the metes and bounds of the invention are unclear. It is unclear what applicant's actual invention is because it is unclear what actual "stem cells" are used in the invention or what the actual cells of the graft are when they are used for repair. Applicant's claims don't require differentiation however many of the claims require "maturation" and "penetrance" which would appear to involve differentiation. It would also appear that the ultimate graft useful for tissue repair would contain differentiated cells yet the claims are drawn otherwise. Applicant should clarify the invention and distinctly claim it.

Please note that the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds". See, e.g., the following decisions: *In re Hammack*, 427 F.2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); *In re Venezia* 530 F.2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); *In re Goffe*, 526 F.2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); *In re Watson*, 517 F.2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); *In re Knowlton* 481 F.2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: *In re Steele*, 305 F.2d. 859, 134 USPQ 292

(CCPA 1962); In re Moore 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

Claims 16, 27 & 47 are dependent on a cancelled claim and thus the limitations are unclear.

Applicant, in claims 3 & 27, claims that the stem cell is a bone marrow stromal cell which is confusing in that the cell types are distinct and diverse.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 10, 13 & 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al (5695998).

Badylak et al (Col 6) teach seeding cells, including stem cells, on intestinal submucosa thus creating a graft (as is claimed). The reference discusses that stem cells can be proliferated, expanded and/or differentiated on the graft. The claims contain the

limitations "mucosal surface" and "serosal surface" which only have the effect of saying that the submucosa has a top layer and a bottom layer, which clearly the submucosa of Badylak must have. Badylak calls the surfaces, the luminal and abluminal surfaces and explains that the cells can be seeded on either side (Col 4). Badylak doesn't call the seeded material "A urinary tract tissue graft" however the elements of the claim are the same as those taught by the references. The specific tissue used for the graft is taught to be from the small intestine of a pig by the method of the incorporated 4902508 and is taught to be clamped on a frame to create a flat surface. The reference anticipates the claim subject matter.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6, 7, 10, 13, 24, 25 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (as cited above) and in view of Zhang et al (*Pediatrics Journal* 1999 & *Journal of Urology* 2000).

Even if Badylak were read not to clearly envisage the invention rejection above in the § 102 clearly are strongly suggested by Badylak and one of ordinary skill in the art at the time the invention was made would have been motivated by the teachings of Badylak to make a tissue graft as is claimed because, as set forth in the above rejection, the patent clearly teaches the elements of the invention and as a whole provides motivation to make the claimed graft for the purpose of tissue engineering and repair.

Any differences in the claimed invention and what is disclosed by Badylak would have been obvious at the time the invention was made as a matter of routine experimentation and optimization.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was



performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");< \*\* In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Claims 44, 45 & 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (as cited above) and in view of Zhang et al (*Pediatrics Journal* 1999 & *Journal of Urology* 2000).


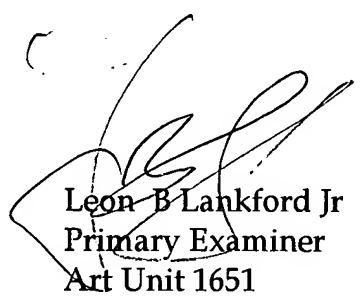
Badylak does not disclose using their tissue graft for the repair of the urinary tract, however as the patent does disclose that the seeded submucosa is a tissue graft and because Zhang et al (*Pediatrics Journal* 1999 & *Journal of Urology* 2000) teaches using a cell-seeded SIS for the repair of urinary tract tissue it would have been obvious at the time the invention was made to use of the graft of Badylak as a graft for urinary tract tissue with a reasonable expectation that repair would be facilitated.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B Lankford Jr  
Primary Examiner  
Art Unit 1651

LBL